REMARKS

Claim 5 is objected to for a grammatical error, namely the inadvertent inclusion of the word "of". Claim 5 has been amended to correct the error. Consequently, applicants respectfully request this objection be withdrawn.

Claims 1-3, 5, 8-10, 14, and 19-24 are finally rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,858,154, in view of U.S. Patent No. 6,512,986. Specifically, the Examiner states that: 1) the '986 patent discloses performing the evaluation within an analytical instrument; 2) the '154 patent discloses the claimed invention except for performing the evaluation within an analytical instrument; and 3) it would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the evaluation within an analytical instrument, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art. Applicants respectfully disagree with the characterization of the references and the rejection based thereon.

When an application is submitted to the Patent and Trademark Office, statute[1] and case law[2] dictates that the burden of proof is on the PTO to establish a prima facie case of obviousness.[3] Once the prima facie case has been established, then the burden of going forward with the evidence to rebut the prima facie case shifts to the applicant.[4] Only the burden of going forward with evidence to rebut shifts to the applicant, however. The burden of persuasion remains with the PTO.[5] In this instance, a prima facie case would necessarily

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[1] 35 U.S.C. 132.

[2] See In re Warner, 154 USPQ 173, 178 (C.C.P.A. 1967); In re Oetiker, 24 USPQ 2d 1443, 1447 (Fed. Cir. 1992).

[3] In re Piasecki, 223 USPQ 785, 788 (Fed. Cir. 1984).

[4] In re Carleton, 202 U.S.P.Q. 165,168 (CCPA 1979).

[5] Ashland Oil v. Delta Resins and Refractories, Inc., 227 U.S.P.Q. 657, 659 (Cir. Fed. 1985). See also In re Fritch, 23 U.S.P.Q.2d 1780, 1783 (Cir. Fed. 1992): "In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. `[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the

have to first establish that the combined teachings of the '154 and '986 patents render the claimed subject matter obvious[6], and second provide a suggestion or motivation within the cited references to combine the cited references to arrive at the claimed invention.[7] The suggestion or motivation to combine the references must not be a hindsight reconstruction of isolated disclosures within the prior art.[8] Indeed, the lack of an appropriate motivation or suggestion to combine gives rise to an inference that the combination is the product of hindsight.[9]

The '154 patent discloses an "Interlaboratory Quality Assurance Program". In the "Summary of the Invention" section, the '154 patent discloses that "[t]his invention is an improved procedure for evaluating the accuracy and/or precision of at least one apparatus in a pool of like apparatuses with respect to the arithmetic mean accuracy and/or precision of the performance of all the apparatuses in the pool." (col.2, lines 62-67) The '154 patent discloses further:

> The novel procedure of this invention involves quantitatively analyzing a reference or cell control specimen of known constituents by each apparatus in the pool and collecting the resultant data from the one apparatus in the pool and the arithmetic mean data of the pool apparatus. The data of the one apparatus and of the pool apparatuses are correlated mathematically in a series of statistical equations for computing a novel, sensitive index herein named the [IPI]... This IPI permits an operator of the one apparatus to determine readily the degree of accuracy and/or

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references.' The patent applicant may then attack the Examiner's prima facie determination as improperly made out, or the applicant may present objective evidence tending to support a conclusion of nonobviousness.",.

[6] In re Wood, 202 USPQ 171, 174 (C.C.P.A. 1979) citing In re Bozek, 163 USPQ 545, 549-550 (C.C.P.A. 1969).

[7] ACS Hosp. Systems, Inc. v. Montefiore Hosp., 221 USPQ 929, 933 (Fed. Cir. 1984), "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent som e teaching or suggestion supporting the combination. Under section 103, teachings of references can only be combined if there is some suggestion to do so."

[8] In re Fritch, 23 USPQ2d 1780 (Fed. Cir. 1992), "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention", quoting In re Fine, 5 USPQ2d 1596 , 1600 (Fed. Cir. 1988).

[9] In re Rouffet, 47 USPQ2d 1453, 1458 (Fed. Cir. 1998).

precision... of the one apparatus as compared to the accuracy and/or precision of the pool of apparatuses." (Col. 3, lines 3-21)

The '986 patent discloses a "Method for Automated Exception-Based Quality Control Compliance for Point-Of-Care Devices." FIG. 1 is a schematic diagram illustrating the interaction between the basic units of the system. (Col.5, lines 55-56) The basic units of the system include a POC device(s) 108 and a database 104. FIG.1 shows the POC device apart from the computer (including the database) and depicts two lines of communication between the POC device 108 and the database 104; i.e., a line of communication 3 from the POC device 108 to the database, and a line of communication 33 from the database 104 to the POC device. "The database 104 maintains all the rules and stores all of the information from the devices because such storage is necessary in a highly distributed operating environment." (col.6, lines 15-18) The POC device 108 "stores each test result associated with a particular operator and a particular reagent lot as well as the results from the standardized test, and on a periodic (to "real-time") basis transmits those results to the database 104 for storage." (col.7, lines 12-17) "There is also, of course, a data flow from the database back to the device 108 represented by line 33." As shown in FIG.1, the database is in communication with "automatic processing". The specification indicates that step 5 "is the transfer of QC results from the database for automatic processing. The processing system 110 comes into play at this point and must process the data by comparing statistical calculations performed on the data to the rules." (col.7, lines 45-49). The processing system is shown within the "computer" portion of the FIG.1 diagram.

Claims 1 and 19 of the present application, in contrast to the cited references, recite a method for providing quality control in an analytical instrument that comprises the steps of, inter alia:

analyzing the quality control specimen using the analytical instrument and thereby creating instrument analysis data;

performing an evaluation within the analytical instrument of the instrument analysis data relative to the control data to determine a functional status of the analytical instrument;

The '154 patent is quite clear that the "apparatus" (i.e., analytical instrument") is the device in which the sample is analyzed. Examples provided within the '154 patent include hematology analyzers (e.g., "COULTER COUNTER") and chemical analyzers (e.g., "COULTER DACOS"). (see cols. 1 and 7) "Raw data" from each apparatus is, in turn, sent to an "IQAP Processing Center" where it is collectively analyzed to determine the arithmetic mean accuracy and/or precision of the performance of all the apparatuses in the pool:

> The IQAP processing center then would compile all of the data, perform the computations to obtain the CVI, SDI and IDI, preferably generate the IPI plots shown in FIG.4, as well as the data of Table II discussed below and, where needed, give guidance to each laboratory for improving the precision and accuracy of its apparatus and its system. (see col.8, lines 50-68 to col.9, line 1)

Hence, the quality assurance method disclosed within the '154 patent does not include a method having a step of a first step of "analyzing at least one of the one or more quality control specimens using the analytical instrument and thereby creating instrument analysis data", and a subsequent step of "performing an evaluation within the analytical instrument of the instrument analysis data relative to the control data". In fact, the method disclosed within the '154 patent requires interactive communication with a pool of like apparatuses and the evaluation is performed wholly apart from the instrument.

In similar manner, the method disclosed within the '986 patent is quite clear that the POC devices that must be evaluated for quality control purposes are in communication with, but separate from the computer. The diagram of the system shown in FIG.1, clearly shows the POC devices outside of the "computer(s)" that include the database, rules, automatic processing, etc. As detailed above, each POC device stores

test results produced within that POC device, and on a periodic basis transmits those results to the database for storage. The database, in contrast, maintains all the rules and stores all of the information from the POC devices, and includes a processing system that processes the results by comparing statistical calculations performed on the results to the rules.

Hence, it is quite clear that the method disclosed within the '986 patent does not include a method having a step of a first step of "analyzing at least one of the one or more quality control specimens using the analytical instrument and thereby creating instrument analysis data", and a subsequent step of "performing an evaluation within the analytical instrument of the instrument analysis data relative to the control data".

Neither of the references, therefore, discloses the steps recited within independent claims 1 and 19 of the present application. Consequently, the combined teachings of the '154 and '986 patents do not disclose the method claimed within present claims 1 and 19 and therefore cannot render the claimed subject matter obvious.

The rejection does not explicitly state how the references are to be combined to arrive at the claimed invention, nor any suggestion or motivation to make such a combination. The Examiner does state that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the evaluation within an analytical instrument, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art." The relevance of the aforesaid statement is unclear. What manual activity is being replaced? Applicants respectfully request clarification.

The present method recites the steps of "analyzing at least one of the one or more quality control specimens using the analytical instrument and thereby creating instrument analysis data", and a subsequent step of "performing an evaluation within the analytical instrument of the instrument analysis data relative to the control data". Consequently, the analysis and evaluation are both performed within the same analytical instrument and can be performed anywhere, without connection to other apparatus or a central database. This characteristic provides significant advantages. Point-of-care devices are typically used in a variety of different environments, many of which do not allow for connection to

another apparatus or a central database. The present invention allows for quality control procedures without connection to another apparatus or a central database. Another advantage is the ease of administering the quality control procedure. Under the present invention, there is no connection to another apparatus or a central database. Consequently, the requirement to make the connection and the possibility for error in such connection is eliminated.

Claims 2, 3, 5, 8-10, and 14 depend from claim 1. For the reasons provided above relative to claim 1, applicants respectfully submit that claims 2, 3, 5, 8-10, and 14 are patentable in view of the cited references. Applicants, therefore, request these claims be allowed and passed onto issuance.

Independent claim 20 and dependent claims 21-23 recite a quality control system for analytical instruments that comprises "an analytical instrument, having an analyzer for analyzing the one or more quality control specimens, and thereby create instrument analysis data that includes one or more sensed characteristic values" and "means for performing an evaluation of the analytical instrument within the analytical instrument using the instrument analysis data and the predetermined characteristic values to determine a functional status of the analytical instrument". For the reasons provided above relative to claims 1 and 19, applicants respectfully submit that claims 20-23 are patentable in view of the cited references. Applicants, therefore, request claims 20-23 be allowed and passed onto issuance.

Claim 24 of the present application recites a method for providing quality control in an analytical instrument that comprises the steps of, *inter alia*, "analyzing at least one of the one or more quality control specimens and thereby creating instrument analysis data" and "performing an evaluation within the analytical instrument of the instrument analysis data relative to the control data to determine a functional status of the analytical instrument". For the reasons provided above relative to claims 1 and 19, applicants respectfully submit that claim 24 is patentable in view of the cited references. Applicants, therefore, request claim 24 be allowed and passed onto issuance.

Claims 1, 19, and 20 are provisionally rejected under the judicially created doctrine of obvious-type double patenting. Claims 1, 19 and 20 are currently rejected. When claims 1, 19 and 20 are allowed, applicants will submit an appropriate terminal disclaimer.

As applicants have traversed each rejection and objection raised by the Examiner, it is respectfully requested that the Examiner withdraw the stated rejections and objections, allow claims 1-3, 5, 8-10, 14, and 19-24, and pass the present application on to issuance. No fee is believed due with this response. In the event a fee is due, however, please charge our Deposit Order Account No. 50-3381.

Respectfully submitted,

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